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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,646	03/24/2006	Ahmad Oulmouden	0508-1156	2195
466 7590 08/05/2008 YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			EXAMINER KAPUSHOC, STEPHEN THOMAS	
			ART UNIT 1634	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/565,646

**Applicant(s)**

OULMOUDEN ET AL.

**Examiner**

Stephen Kapushoc

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-43 is/are pending in the application.
- 4a) Of the above claim(s) 20-29, 31, 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 32-34 and 37-43 is/are rejected.
- 7) ☒ Claim(s) 37 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/808)
- Paper No(s)/Mail Date 1/24/2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-19 are cancelled.

Claims 20-29, 31, 35 and 36 are withdrawn from examination as detailed below.

Claims 30, 32-34, and 37-43 are examined on the merits.

### ***Election/Restrictions***

1. Applicant's election of the invention of Group 2, and the further Election of the *si* allele of SEQ ID NOs: 3 and 8, in the reply filed on 05/02/2008 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-29, 31, 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (i.e. drawn to non-elected method claims, and drawn to nucleic acids requiring non-elected sequences), there being no allowable generic or linking claim.

### ***Claim Objections***

2. Claim 37 is objected to over the specific recitation of the phrase 'a method according to claim 20', where Applicants have elected for the examination of claims drawn to nucleic acid products, and claim 20 is withdrawn from examination.

3. Claim 42 is objected to because of the following informalities:

Claim 42 is objected to over recitation of the phrase 'where nucleotide sequence consists' where the phrase 'where said nucleotide sequence consists' is correct.

Appropriate correction is required.

***Objection to the Specification – Sequence Compliance***

4. This application (10/565,646) contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 at least for the reason(s) set forth below:

In the case of the instant Application, Figures 1-4 of the drawings contain biological sequences that are not identified by SEQ ID NO, and in the case of the RPE1 sequences of Figs 3 and 4 do not appear to be included in the sequence listing.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must include all sequences presented in the application in the Sequence Listing, and clearly identify each sequence from the sequence listing by reference to the appropriate SEQ ID NO from the Sequence Listing.

**In order for any response to this Office Action to be considered fully responsive, the response must put the application in compliance with the sequence rules.**

***Claim Rejections - 35 USC § 101 - Product of Nature***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 30, 32, 33 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter. Because the claims read on polynucleotides that would occur in nature, untouched by the hand of man, the claims, as broadly drawn, encompasses non-statutory subject matter. For example, the broadly claimed polynucleotides of the claims would be included in the naturally occurring bovine genome, where for example the broadly claimed primers of claim 33 would be found during replication of the genome during cell division. It is noted the rejection is not applied to claim 34 (which requires that a primer of the claimed primer pair is labeled), claim 37 (which requires that the claimed primers are part of a kit), or claims 38-43 (which require that the claimed nucleotide sequences are isolated).

This rejection may be overcome by amendment of the claims to include, for example, language clarifying that the claims are drawn to polynucleotides that are isolated.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 34 are unclear over recitation of the phrases 'said derived sequence being hybridized, like the sequence of SEQ ID NO: 10' (in lines 10-11 of

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claim 32 and lines 8-9 of claim 34) and 'said derived sequence being hybridized, like the sequence of SEQ ID NO: 11' (lines 21-22 of claim 32 and lines 19-20 of claim 34). The portions of each claim preceding each unclear phrase recites the sequence of SEQ ID NO: 10 and 11, but does not require that either of SEQ ID NO: 10 or 11 is in fact hybridized to anything. Because the sequences of SEQ ID NO: 10 and 11, as recited in the claim, are not required to be hybridized to anything, it is unclear what is required of the derived sequences with regard to the limitation that the claimed derived sequences are 'hybridized, like the sequence of SEQ ID NO: 10' or 'hybridized, like the sequence of SEQ ID NO: 11'.

### ***Claim Rejections - 35 USC § 102***

In the rejection of claims in view of the prior art, the breadth of the claims is noted.

Claim 30 is broadly drawn to a nucleotide sequence that 'corresponds' to (where the term corresponds is not a transitional phrase, such as comprising or consisting (see MPEP 2111.03, that requires any specific nucleotide content) any of: (i) the bovine *si* gene represented by SEQ ID NO: 3 (where the term 'represented by' does not require any specific nucleotide content); (ii) a fragment containing the nucleotides situated in positions 82 to 93 of the sequence SEQ ID NO: 3 (where the limitation requires only the nucleotides (i.e. the particular monomers of the recited positions) and does not require, for example the nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3).

Claim 32 encompasses nucleotide sequences of any sequence (i.e. any sequence derived from SEQ ID NO: 10 or 11 by the suppression and/or substitution and/or addition of one or more nucleotides) with the broad limitation that the claimed nucleic acid sequence is hybridized (it is noted that the requirement of hybridization is addressed earlier in this Office Action under 35 USC 112 2nd ¶) with any part (i.e. as little as a single nucleotide) of a sequence delimited by positions 9 and 38 or 276 and 302 of SEQ ID NO: 3.

The primers of the primer pair of claim 33 are limited only in that they comprise approximately 10 to approximately 30 nucleotides. The primers are hybridized to sequences broadly required to be of approximately 10 to approximately 30 nucleotides and complementary to positions 1-60 of SEQ ID NO: 3, and the sequence between positions 94 to the last of the nucleotides of SEQ ID NO: 3. The primers of claim 34

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(where claim 34 depends from claim 33) encompass primers hybridized to nucleic acid sequences with the same breadth as the limitations of claim 32, as addressed above.

The kit of claim 37 requires primers with the same broad structural limitations as those set forth in claim 33, as addressed above. Furthermore it is noted that the intended use of the claimed kit, as set forth in the preamble, as 'for the implementation of a method according to claim 20' is not given patentable weight in the examination of the required structural limitations of the claimed kit in view of the prior art. As noted in the MPEP 211.02:

'a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone'.

Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation". Further regarding the limitations of claim 37, it is noted that the in the recitation 'and if appropriate the reagents necessary for the implementation of the amplification reaction of the number of copies of the different allelic forms of the *SILVER* gene' the phrase 'and if appropriate' indicates that 'the reagents necessary for the implementation of the amplification reaction of the number of copies of the different allelic forms of the *SILVER* gene' are optional and not a requirement for the claimed kit.

Claims 38-43 are drawn to isolated nucleic acid sequences which are limited to, for example in claim 38, comprising the nucleotides 82-93 of SEQ ID NO: 3. The limitations of the claims require only the nucleotides (i.e. the particular monomers) of the various recited positions. The claims thus do not require a particular sequence of nucleotides. For example, where the claims require that a sequence comprises the nucleotides of SEQ ID NO: 3, the limitation requires only that the claimed sequence comprises A, C, G, and T nucleotides.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 30, 32, 33, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Maresh et al (1994).

Maresh et al teaches the analysis of the cDNA sequence encoding the human ME20 antigen. Considering the breadth of the claim limitations, as detailed earlier in this Office Action, the nucleic acids of Maresh et al anticipates the rejected claims.

Regarding claim 30, Maresh et al teaches a nucleotide sequence of the human ME20 cDNA (Fig 2A), where the sequence is comprised of A, C, G, and T nucleotides. Thus the sequence of Fig 2A of Maresh corresponds to a fragment of approximately 10 nucleotides containing the nucleotides situated in positions 82 to 93 of the sequence of SEQ ID NO: 3 (e.g. the sequence of Maresh contains the 10mer 5'-CTCGAGATGG-3' at positions 1-10 of Fig 2A, which is comprised of the nucleotides A, C, G, and T).

Regarding claim 32, Maresh et al teaches (p.88 – Cloning of ME20 antigen by polymerase chain reaction; Fig 2A) an oligonucleotide 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' that is used to amplify the cDNA of Fig 2A. Relevant to the limitations of claim 32, the aforementioned oligonucleotide of Maresh et al is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 20 of SEQ ID NO: 10 with the nucleotide sequence from position 1 to position 14 of the of the oligonucleotide of Maresh et al, and the addition the nucleotide sequence 5'-GTG CTA AAA AGA TGC CTT C-3' to the 3—end of sequence of SEQ ID NO: 10. While the limitation that the derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2<sup>nd</sup> ¶, the oligonucleotide of Maresh et al is used in a polymerase chain reaction, wherein the primer is hybridized to its complementary sequence, where its complementary sequence includes 5'-



AGATCCATC-3' (i.e. complementary to positions 15-23 of the oligonucleotide of Maresh et al) and that complementary sequence is also the complement of the sequence set forth in SEQ ID NO: 3 between positions 30 and 38. Thus in the PCR of Maresh et al the disclosed oligonucleotide satisfies the broad structural limitations of the claimed nucleotide sequence, and is hybridized to part of the nucleotide sequence complementary to the nucleotide sequence delimited by the nucleotides situated in positions 9 and 38 of SEQ ID NO: 3.

With regard to the claimed primer pair of claims 33 and 37, Maresh et al teaches PCR amplification of the ME20 cDNA of Figure 2A using a first primer 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' and a second primer 5'-GTA TTA GCG GCG GCA ATC ACA GCA TCA TAT GAG AGC TC-3'. During the PCR amplification of the cDNA the aforementioned primers are hybridized to their complementary sequences on opposite strand templates and extended to the end of the template, where the extended primer is itself a primer that comprises (i.e. may have any amount of any additional elements, including additional nucleotides) approximately 10 to approximately 30 nucleotides. Relevant to the limitation that one of the claimed primers is hybridized with a sequence of approximately 10 to approximately 30 nucleotides comprised in the nucleotide sequence complementary the sequence delimited by the nucleotides situated in positions 1 and approximately 60 of the nucleotide sequence of SEQ ID NO: 3, the first primer hybridizes to its complementary sequence including 5'-AGCACCAGATCCATC-3' (i.e. the complement of positions 15-29 of the first primer of Maresh et al), where the sequence is the complement of the sequence of positions 30-

44 of SEQ ID NO: 3. Relevant to the limitation that one of the claimed primers is hybridized with a sequence of approximately 10 to approximately 30 nucleotides comprised between the nucleotide situated in positions 94 and the last of the nucleotides of SEQ ID NO: 3, the extended second primer hybridizes to the sequence of Fig 2A of Maresh et al including 5'-GACTGGCTTGGTGTCTCAAGGCA-3' (i.e. positions 97-119 of the cDNA of Maresh et al), where the sequence is identical to the sequence of positions 2340-2362 of SEQ ID NO: 3. Relevant to claim 37, Maresh et al teaches a collection of nucleic acids, which is a kit (where it is noted that the specification sets forth no limiting definition regarding what is required for any collection of reagents to be a kit). The limitations of the primer pair of the kit of claim 37 are the same as the primer pair of claim 33, which have been addressed.

Regarding claims 38-43, as addressed previously, the language of the claims requires only that the claimed nucleotide sequences comprise (i.e. claims 38-40) and consist (claims 41-43) of the nucleotides of various portions of SEQ ID NO: 3. As the limitations of the claims address only the nucleotides (i.e. the monomers) of the recited positions of SEQ ID NO: 3, and do not require any particular contiguous sequence from SEQ ID NO: 3, the cDNA sequence of Maresh et al (Fig 2A) satisfies the limitations of the rejected claims as the sequence of Maresh et al is composed of the nucleotides A, C, G, and T, where the same nucleotides are in SEQ ID NO: 3 as recited in the claims.

11. Claims 30, 32, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank GI 412525 (1993).

Regarding claim 30, GenBank GI 412525 teaches a nucleotide sequence of a 99bp DNA where the sequence is comprised of A, C, G, and T nucleotides. Thus the sequence of GenBank GI 412525 corresponds to a fragment of approximately 10 nucleotides containing the nucleotides situated in positions 82 to 93 of the sequence of SEQ ID NO: 3 (e.g. the sequence of GenBank GI 412525 contains the 12mer 5'-TTCTGCTGTAA-3' at positions 17-28, which is comprised of the nucleotides A, C, G, and T). While the examiner has set forth that the claim does not require the contiguous nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3, in the interest of customer service and compact prosecution it is noted that aforementioned 12mer is in fact identical to positions 82-93 of SEQ ID NO: 3.

Regarding claim 32, GenBank GI 412525 teaches a DNA sequence of 99 nucleotides that, relevant to the breadth of the limitations of claim 32, is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 30 of SEQ ID NO: 10 with the nucleotide sequence as set forth in GenBank GI 412525. While the limitation that the derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2<sup>nd</sup> ¶, the sequence of GenBank GI 412525 is a double stranded DNA sequence (i.e. the reference indicates it is 99bp, thus base paired) thus hybridized to its complementary sequence, where its complementary sequence includes 5'-TTCTT-3' (i.e. complementary to positions 28-32 of GenBank GI 412525) and that complementary sequence is also the complement of the sequence set forth in SEQ ID

NO: 3 between positions 21-25. Thus the 99bp DNA molecule of GenBank GI 412525 satisfies the broad structural limitations of the claimed nucleotide sequence.

Regarding claims 38-43, as addressed previously, the language of the claims requires only that the claimed nucleotide sequences comprise (i.e. claims 38-40) and consist (claims 41-43) of the nucleotides of various portions of SEQ ID NO: 3. As the limitations of the claims address only the nucleotides (i.e. the monomers) of the recited positions of SEQ ID NO: 3, and do not require any particular contiguous sequence from SEQ ID NO: 3, the DNA sequence of GenBank GI 412525 satisfies the limitations of the rejected claims as the sequence of GenBank GI 412525 is composed of the nucleotides A, C, G, and T, where the same nucleotides are in SEQ ID NO: 3 as recited in the claims. As detailed above, while the examiner has set forth that the claim does not require the contiguous nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3, in the interest of customer service and compact prosecution it is noted that 12mer 5'-TTCTGCTGTAA-3' at positions 17-28 of GenBank GI 412525 is in fact identical to positions 82-93 of SEQ ID NO: 3.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maresh et al (1994) in view of Sarka et al (1997).

Maresh et al teaches PCR amplification of the ME20 cDNA of Figure 2A using a first primer 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' and a second primer 5'-GTA TTA GCG GCG GCA ATC ACA GCA TCA TAT GAG AGC TC-3'. During the PCR amplification of the cDNA the aforementioned primers are hybridized to their complementary sequences on opposite strand templates and extended to the end of the template, where the extended primer is itself a primer that comprises (i.e. may have any amount of any additional elements, including additional nucleotides) approximately 10 to approximately 30 nucleotides. Furthermore, the first

primer hybridizes to its complementary sequence including 5'-AGCACCAGATCCATC-3' (i.e. the complement of positions 15-29 of the first primer of Maresh et al), where the sequence is the complement of the sequence of positions 30-44 of SEQ ID NO: 3. Additionally the extended second primer hybridizes to the sequence of Fig 2A of Maresh et al including 5'-GACTGGCTTGGTGTCTCAAGGCA-3' (i.e. positions 97-119 of the cDNA of Maresh et al), where the sequence is identical to the sequence of positions 2340-2362 of SEQ ID NO: 3. Thus Maresh et al teaches all of the limitations of claim 33, from which rejected claim 34 depends.

Regarding the limitations of rejected claim 34, the nucleic acids taught by Maresh et al, as detailed above satisfy the broad limitations of the nucleotide sequence requirements of the claim. For example, the first oligonucleotide 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' that is used to amplify the cDNA of Fig 2A is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 20 of SEQ ID NO: 10 with the nucleotide sequence from position 1 to position 14 of the of the oligonucleotide of Maresh et al, and the addition the nucleotide sequence 5'-GTG CTA AAA AGA TGC CTT C-3' to the 3—end of sequence of SEQ ID NO: 10. While the limitation that a derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2<sup>nd</sup> ¶, the first oligonucleotide of Maresh et al is used in a polymerase chain reaction, wherein the primer is hybridized to its complementary sequence, where its complementary sequence includes 5'-AGATCCATC-3' (i.e. complementary to positions 15-23 of the oligonucleotide of Maresh

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et al) and that complementary sequence is also the complement of the sequence set forth in SEQ ID NO: 3 between positions 30 and 38. Additionally, the extended second primer of Maresh et al is derived from the sequence as set forth in SEQ ID NO: 11 by substitution of the nucleotide sequence from position 1 to position 30 of SEQ ID NO: 11 with the complement of the nucleotide sequence of the Fig2A of Maresh et al, and the extended primer hybridizes to the sequence of Fig 2A of Maresh et al including the sequence 5'-TTGG-3' (i.e. positions 104-107 of the cDNA of Maresh et al), where the sequence 5'-TTGG-3' is identical to the sequence of positions 294-297 of SEQ ID NO: 3.

Thus in the nucleic acids of the PCR of Maresh et al satisfy the broad structural limitations of the claimed primer pair of rejected claim 34. Furthermore the nucleic acids are hybridized to part of the nucleotide sequence complementary to the nucleotide sequence delimited by the nucleotides situated in positions 9 and 38 of SEQ ID NO: 3 (i.e. the first primer of Maresh et al), and hybridized to part of the nucleotide sequence delimited by the nucleotides situated in positions 276 and 302 of SEQ ID NO: 3.

Maresh et al does not teach that that a primer is labelled.

However, the labelled nucleic acid primers were well known in the art at the time the invention was made.

Sarkar et al teaches a radioactively labelled primer as part of a primer pair used for sequencing a PCR product (Fig 1; p.272 – Direct sequencing by SECS).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have radioactively labelled the first primer of Maresh et

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al, as taught by Sarkar et al, and used the labelled primer in the primer pair as taught by Maresh et al to perform sequence analysis by SECS as taught by Sarkar et al. One would have been motivated to label the primer of Maresh et al and use it in the sequencing methods of Sarkar et al, which would result in the required primer pair of the rejected claim, because Maresh et al teaches that the sequence of the Amplified cDNA was determined by dideoxynucleotide termination sequencing (p.88 – DNA sequence analysis of HF12-2), and Sarkar et al teaches that the methods of sequencing of Sarkar et al are based on dideoxy termination (p.272 – Direct sequencing by SECS), more efficient than alternative methods (p.274 – Application of SECS to screening projects), and should always produce better sequencing results than any conventional cycle sequencing (p.276, right col., part 16).

### ***Conclusion***

16. No claim is allowable. No claim is free of the teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/  
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